SUPREME COURT, U. S.

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No. 343

IN THE

Supreme Court of the United States

OCTOBER TERM, 1968

UNITED STATES OF AMERICA,
Petitioner,

v.

AN ARTICLE OF DRUG * * * BACTO-UNIDISK * * *

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

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BRIEF FOR CLAIMANT DIFCO LABORATORIES, INC. IN OPPOSITION

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A) is reported at 392 F.2d 21. The opinion and findings of fact and conclusions of law of the district court (Pet. App. B) are not reported.

JURISDICTION

The judgment of the court of appeals (Pet. App. C) was entered on March 29, 1968. On June 18, 1968, Mr. Justice Stewart extended the time for filing a petition for a writ of certiorari to and including July 26, 1968. On August 13, 1968, time for filing a brief in opposition to the petition was extended to and including September 25,

1968. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether a sensitivity disk utilized as part of a laboratory testing procedure which yields information the physician may use as a guideline to the changing or selection of an antibiotic to treat patients who have not responded to initial therapy, is a "drug" within the meaning of Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act and, if it is a "drug", whether it is subject to batch certification under Section 507 of the Act.

STATUTE INVOLVED

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), as amended, 21 U.S.C. 301, et seq., provides in part:

Sec. 502 (21 U.S.C. 352)

A drug or device shall be deemed to be misbranded—

(a) if its labeling is false or misleading in any particular.

Sec. 505 (21 U.S.C. 355)

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the

methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug. * * *

STATEMENT

Petitioner's statement of the case does not accurately reflect the facts material to the question here presented.

The history of antibiotic certification (Pet. 5-6), indicates that there was a need for certification of antibiotic drugs because of variability of product and the side effects associated with some such drugs. The drugs involved were, however, those administered to or applied to patients and it was on the basis of this use that Congress provided for certification. The Bacto-Unidisk is not administered to or applied to patients. The history recited in the petition is therefore irrelevant to the question of certification of the disks and lends no support to petitioner's attempt to find a public health issue in this case, *viz.*, the alleged need for certification of sensitivity disks to avoid danger to the health of patients. As will be shown hereinafter, the two witnesses of Petitioner questioned on the matter were unable to support this position at the trial and a third witness affirmatively rejected it as invalid.

The case then becomes merely one of statutory interpretation.

The question decided in the courts below was whether sensitivity disks are used in the diagnosis or treatment of disease and are, therefore, drugs within the meaning of Sec. 201(g)(1)(B) (21 U.S.C. 321(g)(1)(B)). Both courts held that they were not so used and therefore were not drugs.

It was also held below that "drug" must be limited to articles considered by the medical profession as drugs, since no other concept of the term was presented to Congress or described by Congress in the legislative record of the statute. The medical profession, as the testimony shows, regards as drugs only those articles which are administered to the patient or applied to the body in some way.

ARGUMENT

Introduction

The statement in the petition of the Question Presented (Pet. 2) is inaccurate and misleading.

Thus, to pose the question of whether sensitivity disks "containing various antibiotic drugs" are "antibiotic drugs" under the Act prejudges the very point which petitioner wants this Court to decide. The obvious and necessary implication is that the chemicals on the disks are drugs in some sense, presumably in the common understanding of that term, i.e. that they are medicines (Webster's International Dictionary). The implication is misleading. The chemicals are not available for use as drugs, not being in dosage form and being suitable only for use in laboratory testing procedures.

Moreover the fact that Bacto-Unidisks contain chemicals commonly used as drugs, i.e., antibiotic substances and sulfadiazine, has nothing to do with the question of whether the disk itself is a drug since, as the court of appeals recognized, it is the "intended use" of an article which determines whether it falls within the definition of "drug", i.e., whether it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease (Pet. 4a-5a).[1] Thus, neither the disk itself nor the

[1] As the court of appeals also noted (Pet. 4a), even honey may be a "drug" under the Act if it is intended for use in the treatment of disease within the meaning of Sec. 201(g)(1)(B); but

chemicals with which it is impregnated are drugs unless intended for such use.

The phrase in the Question Presented, "disks which physicians use [2] to select the antibiotic most appropriate to treat a particular patient"; being unqualified, conveys the idea that before an antibiotic is administered by the physician the disk indicates the proper drug to be used for the particular condition of the patient. This is not in accordance with the evidence. It is shown in the Argument that it is not the disk but the information derived from the entire testing procedure which may be used by the physician when he receives it—ordinarily some 24 to 36 hours or more after initial therapy has begun.

The Question Presented in the petition has been restated for the reasons set forth above.

A. The Alleged Public Health Need for Certification

1. The position of the Government as we understand it, is predicated squarely upon the proposition that sensitivity disks should be certified because, if they are not, the health of patients for whom antibiotic drugs are prescribed will be endangered and that, therefore, the definition of "drug" in the Act should be construed to include such disks.

The Government virtually ignores the testimony of the witnesses at the trial (both its own and those of respondent), presumably because that testimony contradicts its

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surely no rational person would suggest that its use in a laboratory testing procedure would constitute a use in the treatment of disease.

[2] This and other references in the petition to the use of the disk by the physician do not reflect the facts. The record clearly shows that the testing referred to is conducted by hospital and other laboratories and rarely by the physician himself. Dr. Keefer said, when asked whether it was "customary or rare" for practicing physicians to conduct sensitivity tests: "I would say from the total number of infections that doctors see and treat, both in their offices and in the home, and many in hospitals, the sensitivity test is not used. It is not used routinely" (R. 93a).

claim that the health of patients may be endangered by uncertified disks.

At the trial the Government attempted unsuccessfully, through two of its witnesses, to show such a public health need. Both admitted on cross-examination that they had not had any experience of harm occurring to a patient because of a sensitivity test using a faulty disk (R. 59a-60a, 64a, 102a).

Dr. Keefer testified affirmatively that he knew of no public health problem connected with the possible inadequacy of sensitivity disks (R. 95a), and that he had experienced no situation where the test was so inaccurate that it resulted in the administration of the wrong antibiotic "because in such instances where such a question may arise, the patient is usually getting one, two, three, and sometimes four antibiotics if he is desperately ill" (R. 96a).

In *United States* v. *Consolidated Laboratories, et al.* (Civil Action No. 63-C-23, D. Ill., March 29, 1963), also involving sensitivity disks, the Court found—

> "13a. There is no evidence of injury to the public from the use of the Multidisks" (160a).

The alleged element of hazard and claim of public health need for certification cannot, therefore, seriously be regarded as an issue in this case. The shallowness of the Government's claim is demonstrated by the fact that, had it been able to produce a witness at the trial to document the claim or even to testify to instances where (either before or after certification was instituted) faulty disks had affected the validity of a sensitivity test, it would surely have done so.

It is wholly unwarranted to state that "The need for assurance as to quality and potency is as great when the

antibiotic is used on a disc as when it is used in a pill or injection" (Pet. 14). It seems incredible that this Court would be asked to accept such a proposition in view of the testimony at the trial and the failure of the Government to produce any data to support its claim.

The fact that the Secretary's (Commissioner's) interpretation of the statute extending its coverage to sensitivity disks, was made in a rule-making proceeding, endows it with no aura of sanctity. The interpretation was just like any other statutory interpretation by an administrative official. Since, as the Court of Appeals said, it involved the question of whether the Bacto-Unidisk is within the jurisdiction of the Secretary under the Act, the decision was subject to reexamination by the courts. It is of interest to note also that the rule-making proceeding in question did not even involve the Bacto-Unidisk.[3]

In any event the "judgment" of the Secretary (Commissioner) upon which such great reliance is placed, was not supported by the evidence adduced at the trial of this case. There is no substance to the arguments advanced by the Government on this point.

2. The argument that the patient may be endangered if sensitivity disks are not certified is carried to the extreme of setting up the unfounded implication that the result of the sensitivity test is used as a guide to the *initial* selection by the physician of an antibiotic or antibiotics.[4] The fact is that, as all witnesses agreed, it is

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[3] The proceeding, and the regulation adopted pursuant thereto, applied to disks containing antibotic substances only and no other kind of chemicals (21 C.F.R. 147.2(a)). The Bacto-Undisk contains sulfadiazine, which is not an antibotic substance. Consequently it could not be certified, unless the combination on the disk of antibiotic substances with sulfadiazine were accepted by the Commissioner as "suitable" (21 C.F.R. 147.2(b)—"Packaging") and after regulations were adopted providing for that combination (21 C.F.R. 146.10).

[4] E.g., the phrase "discs which physicians use to select the antibiotic most appropriate to treat a particular patient" in the statement of the Question Presented, being unqualified, conveys the idea

the common practice for the physician to prescribe one or more antibiotics, on the basis of his clinical experience and information available to him from various sources, before the sensitivity test is run (Finding Number 8, R. 146a-147a; R. 43a, 52a-53a; 90a-91a; 104a).

Since the conditions for which antibiotic drugs are administered are infectious diseases, it is apparent that delay in institution of treatment would be undesirable.

The administration of antibiotics before the completion of the sensitivity test is ordinarily essential since from 24 to 36 hours, and sometimes more, may elapse before the sensitivity test is completed and the results are reported to the physician (assuming the physician has ordered a test at all). The preliminary test by which the organism in the specimen taken from the patient is isolated and identified involves 18 hours of incubation of a plated agar culture medium inoculated with a specimen,[5] and the subsequent sensitivity testing procedure usually requires an additional 18 hours incubation (Finding of Fact Number 7, R. 146a; R. 32a, 91a).[6]

Obviously, institution of treatment can rarely be delayed until completion of these tests. In this sense infections in which antibiotic therapy is indicated may involve

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that, before selection, a sensitivity test is run. The same implication is contained in the discussion on page 7. The correct statement would be, that, if the patient does not respond to the initial therapy, the results of the sensitivity test "might be used as an aid in changing or selecting another antibiotic" (R. 93a).

[5] The publication cited on page 6 of the petition (The Usefulness of In Vitro Sensitivity Tests in Antibotic Therapy, Annual Review of Medicine, Vol. 14, pp. 41-46 (1963)) states that the first principle upon which the rational use of antibiotic drugs should be based is that "the specific identity of the infecting organism must be determined" (p. 41). Dr. Truant testified that the identification procedure requires 18 hours (R. 32a).

[6] The 6 to 18 hours mentioned by Dr. Truant (R. 31a) and in the petition (p. 7) refer only to the sensitivity test itself which, in fact ordinarily takes substantially more than 6 hours (R. 16a, 32a, 91a).

emergency situations within the meaning of Finding of Fact Number 8. As Dr. Lerner, a witness for the Government put it, therapy is "almost always begun before the sensitivity test is completed" (R. 104a). As the court found, the results of the sensitivity test are later used by the physician to confirm his selection of an antibiotic (Finding Number 8, R. 147a).

The testimony and the findings of the district court obviously cannot be reconciled with the blanket statement in the petition (p. 10) that ". . . the labeling for most of the antibiotics available to prescribers tells the physician that his use of these drugs should depend upon the results of *in vitro* culture and sensitivity testing". The footnote (Number 3) to the quoted passage does not support it. The quotation from Physicians' Desk Reference (1968, p. 1173) refers to situations in which Lincocin is used as the sole antibiotic therapy. Obviously, if the patient were desperately ill the physician could not await the result of a sensitivity test to begin therapy with either Lincocin or one or more other antibiotics. Moreover, the footnote fails to indicate that in Supplement B to the 1968 Physicians' Desk Reference the product information has been revised to direct: "Do *in vitro* culture and susceptibility studies *in conjunction* with Lincocin therapy" (Supplement B 27, emphasis supplied). The statement as changed in the supplement is more consistent with medical practice as shown by the testimony at the trial.

B. The Statutory Definition of "Drug" As Applied by the Lower Courts

1. It is stated in the petition (p. 13) that "Despite a contrary suggestion by the court of appeals the discs are clearly used in the cure, mitigation, and treatment of disease". The statement will not stand examination. It is beyond cavil that the word "treatment" as used in Section 201(g)(1)(B) means "treatment of a patient". It seems quite obvious that a disk used only as a part of a test

procedure in a laboratory is not used in the treatment of a patient.

The Court of Appeals held that the Bacto-Unidisk "has nothing to do with the diagnosis or prevention of disease"; that "it is not intended for use either internally or externally to cure, mitigate, or treat disease"; and that "it only aids the physician to determine what antibiotics to use for the cure, mitigation or treatment of disease" (Pet. 3a).

This is in accordance with the evidence. It is clear that the *information* obtained from the *sensitivity test* (not just from the disk) is used as a guideline to treatment of some cases of disease (R. 33a-35a, 50a-51a, 90a-97a). The testimony fully supports the statement in Finding of Fact Number 8 (R. 146a-147a) that: "The information obtained from the sensitivity testing procedure outlined in Finding Number 7 is used by the physician as a guideline to treatment of the patient . . ."

No witness would accede to the Government's suggestions that the disk itself was used, or intended for use, in treatment[7] (E.g. Dr. Truant, R. 74a-75a). When therefore, the Petition refers to disks as "the means of determining which of such drugs [antibiotics] to administer to the patient" (p. 11) it is plainly inaccurate. Indeed, Finding of Fact Number 8 (R. 146a-147a) makes it clear, with respect to the information obtained from the sensitivity test that: "The disk, the culture medium, the Petri plate, and the incubation are all a part of the testing procedure yielding this information"; that "such information could not be obtained from the disk itself"; and that "the test is only one of many sources (such as the physicians experience, clinical symptoms, the litera-

[7] The Government largely abandoned its contention that the disk was used in diagnosis (R. 26a-27a), and does not press it here. The disease cannot be diagnosed (or recognized, R. 88a) until the suspected organism has been identified, and the sensitivity test does not enable one to identify an organism (R. 88a-89a).

ture, and other tests such as urinalysis and blood serum tests) of the information upon which the physician relies in determining the treatment to be administered". It is thus apparent that if the disk is a "drug", so are the culture medium, the Petri plate, and the incubator, as well as the medical literature and materials used in other tests such as urinalysis and blood serum tests (and others employing body specimens).

The District Court found that—

> "In medical science those substances which are for administration to or for use on, a person for the treatment of disease or injury, are regarded as drugs (Tr. 102-103, 195, 199, 261-262, 283). This is the commonly accepted view of physicians generally. A physician who testified for the libelant could think of no example of a substance not taken into or applied to the body which he would 'consider medically' as a drug (Tr. 103)". (Finding Number 9, R. 147a).

The Court also found that "The article does not purport to be and is not represented as a 'drug' as that term is used in medical science or by physicians generally. It is labeled 'For Laboratory Use . . .'". (Finding of Fact Number 11, R. 148a).

These findings are fully supported by the record and are not challenged by the Government. They lend powerful support to the clear purport of the testimony that the disk is not used in the treatment of disease but that the information obtained from the sensitivity test (in which the disk is used) is a guideline to therapy which becomes available some 24 to 36 hours after initial therapy has begun.

The petition offers no standard for determining the scope of the definition of "drug" as an alternative to that of the concept of the term in medical science. The only other available test for applying the definition therefore is that of whether, in the view of the Food and Drug Administration, a given article should be controlled under

the Act. This is neither an orderly nor a reasonable way of determining the coverage of a statute.

The Bacto-Unidisk is a laboratory reagent. There are more than 150 pages in the United States Pharmacopeia (and others in the National Formulary) describing hundreds of laboratory reagents or testing materials for use in making the various tests and assays described in the Pharmacopeia.[8] If the Government's position that sensitivity disks are used in the treatment of disease were sound, the Food and Drug Administration could, on the basis of the same approach, classify many, and perhaps most, of those reagents as "drugs" under the statute.

There is absolutely no warrant for the extension of jurisdiction over these laboratory tools, either in the statute or its legislative history. The proper forum for the Administration to advocate the subjection of sensitivity disks to the Act is the Congress. If the Administration can present a serious basis for statutory coverage of disks it will, as it has heretofore, receive the attention of the national legislature. Instead, during the six years of this litigation, the spectre of danger to health has been repeatedly flaunted without the production of any data to support it.

Finally, if the Government's position were sound the disk could legally be represented in its labeling as suitable for the treatment of disease; for example, "for use in the treatment of bacterial infections". Such a statement would obviously be false and would constitute misbranding under Section 502(a) of the Act (21 U.S.C. 352(a)), which deems a drug to be misbranded "if its labeling is false or misleading in any particular."

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[8] These reagents are not regarded as drugs by the Committees on Revision of the official compendia (Sec. 201(j), 21 U.S.C. 321(j)) and therefore do not appear in the monograph section of the compendia. Thus, they are not "recognized" in the sense of Sec. 201(g)(1)(A). (R. 112a-113a; 115a-117a; 127a-132a).

2. The Courts below did not, as suggested by petitioner (Pet. 12), disregard principles of statutory interpretation set forth by this Court. The statute does contain its own definition of "drug", thereby making that word a term of art (Pet. 13, Note 5). The applicable portion of the definition is, however, composed of words having a technical meaning, i.e., "diagnosis, cure, mitigation, treatment or prevention of disease." Recognizing this fact, *both petitioner and respondent* presented evidence by distinguished medical and scientific witnesses as to the meaning of the word "drug" in terms of the statutory definition, and its application to sensitivity disks. In receiving such evidence, the trial court was following a long-established principle of statutory construction set forth by this Court in a number of cases, *viz.*, resort to expert evidence *aliunde* in order to give meaning to technical statutory language. *Binns et al.* v. *Lawrence*, 53 U.S. 9; *Boston Sand & Gravel Co.* v. *United States*, 278 U.S. 41; *National Labor Relations Board* v. *Coca-Cola Bottling Co.*, 350 U.S. 264.

The Tariff Act of 1846 contained certain technical words descriptive of the shape of glass, e.g., "not cut or moulded". In *Binns*, *supra*, the Court held that the testimony of glass manufacturers at trial as to the meaning of those terms was controlling in applying the provisions of the Tariff Act, stating in part:

> "Where a statute may be ambiguous in its language, or may have reference to facts or conclusions dependent on usage, the influence of opinion or the proof of established usage may be proper or even indispensable, in fixing the just interpretation of the law . . ." 53 U.S. at 18-19.

On this point, Mr. Justice Holmes states in his opinion in *Boston Sand and Gravel*, *supra*:

> "It is said that when the meaning of language is plain, we are not to resort to evidence in order to raise doubts. That is rather an axiom of experience

> than a rule of law, and does not preclude consideration of persuasive evidence if it exists." 278 U.S. at 48.

In a more recent decision this Court reaffirmed the principle that technical words must be given their technical meaning rather than their common, everyday meaning, citing *Boston Sand & Gravel*:

> "If the word be deemed to have a peculiar connotation for those intimate with trade-union affairs, it is incumbent upon us to give the word its technical meaning . . ." *National Labor Relations Board* v. *Coca-Cola Bottling Co.*, 350 U.S. 264, 269.

It is thus clear that the courts below did not disregard principles of statutory construction enunciated by this court. Indeed, petitioner itself agreed at trial that the experts were of help to the Court in this matter (R. 76a). Petitioner cannot now ignore the testimony of its witnesses and respondent's as to the meaning of the word "drug" and urge that because of danger to public health (unsupported by even its own witnesses) sensitivity disks should be classified as drugs.

Securities and Exchange Commission v. *Ralston Purina Co.*, 346 U.S. 119 (Petition 12) is inapposite. There, the offering of securities with respect to which no registration statement was in effect was clearly within the statutory prohibition *unless* it was exempt as "not involving any public offering". The Court, following established principles, placed upon the issuer of the securities the burden of proof of showing that the offering fell within the exemption. The issuer was unable to meet the burden. Here, in contrast, the burden of proof was upon the government to establish that Bacto-Unidisks were "drugs". It failed to do this and now offers its unsupported public health argument as a basis for overturning the findings and decisions of the lower courts.

C. *AMP, Inc.* v. *Gardner*

Petitioner states (Pet. 15) that in *AMP, Inc.* v. *Gardner*, 389 F. 2d 825, 830 (C.A. 2), pending on petition for certiorari No. 86, the Second Circuit rejected the idea that the statute was "restricted to products commonly called 'drugs'", citing also *Bradley* v. *United States*, 264 Fed. 79 (1920), which arose under the Food and Drugs Act of 1906.

The purpose of noting here that the Act is not restricted to products commonly called drugs or to dictionary or pharmacopeia definitions is obscure, since nobody to our knowledge disputes the proposition that it is the "intended use" of the product which determines whether it is a drug (i.e., whether it is for use in the diagnosis or treatment of disease) and the Court of Appeals specifically recognized that principle in the instant case. (Petition 4a-5a). That is why spring water is a "drug" if it is recommended for use in the treatment of disease. (*Bradley* v. *United States*, *supra*).

In its Brief in Opposition to the Petition for Certiorari in *AMP* the Government states with respect to the suture material there involved (p. 7):

> "The essential element, nylon suture material, is recognized as a drug in the official United States Pharmacopeia and therefore is squarely within that portion of the statutory definition which defines as drugs 'articles recognized in the Official United States Pharmacopeia.' Cf. *United States* v. *48 Dozen Packages . . . of Gauze Bandage*, 94 F.2d 641 (C.A. 2)".[9]

In the instant Bacto-Unidisk case the Courts concluded that the disks were not used in the diagnosis or treatment of disease and were therefore not "drugs"; and

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[9] The Gauze Bandage case suggests, and it is our view, that since articles such as sensitivity disks are not "recognized" in an official compendium they are not "of a kind" with the articles which are so recognized and that, therefore, the doctrine of *ejusdem generis* applies to exclude such disks from the definition of "drug".

that, moreover, only substances administered to patients or applied to the body or intended for such use were "drugs". The Brief in Opposition in *AMP* (pp. 8-9) notes that, unlike the disks, the article there involved enters the surgical wound and part of it remains in the body. It also points out (p. 7) that the article is used to ligate or tie off bleeding blood vessels during a surgical operation and that, therefore, it affects the structure or function of the body within the meaning of Section 201(g)(1)(C).

It is fully apparent therefore that there are both legal and factual differences between the instant case and *AMP*, and the Government so states in its Brief in Opposition in *AMP* (pp. 8-9). Even more conclusive, however, is the fact that Petitioner AMP, Inc., unlike Difco Laboratories, did not dispute the proposition that its product was subject to the Act (either as a drug or as a device) and, in the language of the court of appeals, "proceeded to comply with the requirements of the Act relating to devices" (389 F.2d at 826).

AMP, Inc. conceded, therefore, that its product was "intended for use in the diagnosis, cure, mitigation or treatment of disease" or "intended to affect the structure or function of the body", or both, since it would not be a device under Section 201(h) unless it was intended for one or more of such uses. The language relating to diagnosis and treatment (Section 201(h)(1)) and that relating to effect upon the structure or function of the body (Section 201(h)(2)) are common to the definitions of "drug" and "device". The very question in the Bacto-Unidisk case is whether the disk falls within the provision of Section 201(g)(1) which corresponds to Section 201(h)(1), *viz.*, Section 201(g)(1)(B), relating to diagnosis and treatment.

It is obvious, therefore, that the "broad construction" given to the Act in *AMP* is not comparable to that which the Government is seeking with respect to Bacto-Unidisks.

In the former the basic jurisdictional test was concededly met and the question was only one of classification as between "drug" and "device". In the latter the testimony at the trial shows that the basic jurisdictional test, *viz.*, whether the disk is used in the diagnosis or treatment of disease, is not met. In addition, the possible dangers involved in permanent incorporation of a substance into the human body are obviously not present in the case at bar.

D. The Inapplicability of the Certification Provisions (Sec. 507) to Articles Not Administered or Applied to Patients

The petition correctly states that the provision for the certification of antibiotic drugs (Sec. 507, 21 U.S.C. 357) was adopted in order "to adequately insure safety and efficacy of use." Petitioner fails to point out, however, that (1) when Section 507 was enacted in 1945 no antibiotic sensitivity disks were being produced commercially and Congress had never heard of such articles, (2) the language of Section 507 and the applicable legislative history clearly show that the concern of FDA and Congress was to protect patients from the administration of an antibiotic drug (penicillin) which was not safe and efficacious for its intended use.[10] Antibiotic drugs other than penicillin were brought under certification in 1947 and 1949, but there was no deviation from the concept that the purpose of certification was to protect patients to whom such drugs were administered.[11]

In a letter to the President of the Senate the Federal Security Administrator[12] said that the drugs being added to the certifiable list were "highly efficacious for one or more serious diseases", such as rickettsial diseases,

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[10] S. Rep. No. 410 and H. Rep. No. 702, 79th Cong., 1st Sess (1945).

[11] E.g., S. Rep. No. 600, 81st Cong. 1st Sess., (1949), 1949 U.S. Code Congressional Service at 1530-1531.

[12] The predecessor of the Secretary of Health, Education and Welfare.

atypical pneumonia, and virus diseases.[13] Obviously the Administrator was talking about drugs to be used for administration to patients.

In 1962 Section 507 was amended to extend certification to all antibiotics "intended for use by man" (as distinguished from veterinary use).[14]

The words "intended for use by man" and "for human use" are used interchangeably throughout the several committee reports on the bills which became the Drug Amendments of 1962.[15] In the context, they quite clearly refer to use for administration to man by ingestion or otherwise. Thus, the uses of sensitivity disks are clearly excluded, whether the organism being tested by the disk is from man or animal.

The Department of Health, Education and Welfare, under date of October 10, 1962, released a document entitled, "Drug Amendments of 1962, Federal Food, Drug and Cosmetic Act—Summary", which is explicit. It states under "Batch Certification of Antibiotics" that:

> "14. All antibiotic drugs to be *administered to humans* are made subject to batch-by-batch testing and certification by FDA for identity, strength, quality, and purity to assure that they "are safe and effective before they are released for sale." [Emphasis supplied].[16]

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[13] Op. cit. supra., S. Rep. No. 600, U.S. Code Congressional Service at 1531, 1532.

[14] Drug Amendments of 1962, P.L. 87-781, 76 Stat. 780, Sec. 105(a), amending Section 507(a).

[15] S. Rep. No. 1744, Parts I (July 19, 1962) and 2 (August 21, 1962), 87th Cong. 2d Sess., on S. 1552, p. 19 (Part I) and p. 9 (Part 2); H.R. Rep. No. 2464, 87th Cong., 2nd Sess., p. 11 (1962); H.R. Conference Report No. 2526, 87th Cong., 2d Sess., on S. 1552, p. 21 (1962). Part I of the Senate Report and the Conference Report are set out in U.S. Code Congressional and Administrative News, Vol. 2, 1962, at pp. 2884 and 2927.

[16] A subsequently issued printed pamphlet entitled "Summary of the Drug Amendments of 1962" repeats this statement on page 6.

Sensitivity disks, of course, are not "administered" at all. It is evident, therefore, that the Congress, in extending certification authority in the 1962 amendments, and limiting it to antibiotics administered to human beings, was following the pattern established by Section 507 as originally enacted and as reflected in its legislative history.

Moreover, it seems quite clear that the concept of "safety of use" is applicable only to dosage forms of substances which are administered to patients. This is the clear pattern of the statute. Thus, "safety of use" is a statutory test of pre-marketing clearance of a "new drug" under Section 505 of the Act (21 U.S.C. 355). It clearly refers to safety for application or administration to patients.[17]

The concept of safety of use is inapplicable to sensitivity disks, since they are not applied or administered to the patient. It seems clear, therefore, that, even if they were drugs, they would not be subject to certification under Sec. 507.

E. The Bacto-Unidisk as a Device

The suggestion was offered to the lower courts on behalf of respondent that, if the Bacto-Unidisk were subject to the Act at all (respondent contends it is not), it should be treated as a device within the meaning of Sec. 201(h) (21 U.S.C. 321(h)). As a device it would not be certifiable.

The only difference between a drug and a device insofar as the definition of "device" and the pertinent portion of the definition of "drug" (Section 201(g)(1)(B)),

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[17] See, e.g., Report of Special Committee to Review the Policies, Procedures, and Decisions of the Division of Antibiotics and the New Drug Branch of the Food and Drug Administration (approved September 27, 1960); and analysis of H.R. 11581, 87th Cong., 2d Sess., by Department of Health, Education and Welfare, Hearings before the Committee on Interstate and Foreign Commerce, House of Representatives, 87th Cong., 2d Sess., on H.R. 11581 and H.R. 11582 (p. 23).

are concerned, is that devices are "instruments, apparatus and contrivances" and drugs are articles other than instruments, apparatus, and contrivances.[18]

Sensitivity disks are logically classified as "instruments, apparatus, or contrivances," if, contrary to our view, they are to be regarded as used in the "diagnosis, cure, mitigation, treatment, or prevention of disease" or "to affect the structure or any function of the body." As the testimony shows, there is nothing in the nature or manner of use of reagent disks to justify their classification as drugs. It is less difficult to conceive of them as "devices" (assuming that they are subject to the act at all) because they are in fact a "means" or "appliance" within the dictionary definition of the term.[19]

A "generator" supplying chlorine gas for *inhalation* by patients to treat arthritis and sinusitis was considered by the Food and Drug Administration and treated by the Court as a "device" in *United States* v. *22 Devices . . . Halox Therapeutic Generator*, 98 F. Supp. 914 (D. Cal. 1951).

A so-called cancer diagnosis kit with two bottles of common chemicals (one of which was ether, a substance commonly used as a drug), which were to be added to a sample of the patients urine to determine whether cancer was present, was considered to be a "device" and an injunction was granted against its shipment.[20] Likewise, a

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[18] The last clause of Section 201(g)(1) expressly provides that the definition of "drug" does not include devices.

[19] The pertinent definitions in Webster's New International Dictionary are as follows: Device: "1. That which is devised, or formed by design; a contrivance; an invention. . ." Instrument: "1. That by means of which any work is performed or result is effected; a medium; means." Apparatus: ". . . Specif. Any complex instrument or appliance, mechanical or chemical, for a specific action or operation. . ." Contrivance: ". . . 3. A mechanical device; an appliance."

[20] Annual Report of the Food and Drug Administration, 1955, Kleinfeld & Dunn, Federal Food, Drug and Cosmetic Act, 1953-1957, p. 650.

radio diagnostic and treatment machine which was held forth as requiring only a drop of the patient's blood for diagnosis and treatment of various disease conditions, was considered by FDA as a "device", not a drug. The device was seized and a criminal prosecution was brought against its shipper.[21]

It seems manifest that if the disks are drugs because their use involves the testing of organisms from the patient as an aid in deciding upon the proper treatment, the last two devices above described likewise fall into that category. In fact, however, it seems clear that none of the three articles is a drug.

It is useful to recall at this juncture that sensitivity disks are used neither to diagnose a disease or to treat or prevent it. The information derived from them is at most an aid in determining whether the initial therapy should be continued. The disks are therefore distinguishable even from the alleged uses of the devices which have been described.

CONCLUSION

The basis for the Government's position is the proposition that the public health may be endangered if sensitivity disks are uncertified and that, therefore, the definition of "drug" should be interpreted to include such disks. It has been shown that the record fails to support the danger-to-health thesis; that, on the contrary, the testimony contradicts it affirmatively. Consequently, the Government is left only with the question of whether the definition of "drug" may reasonably be construed to apply to sensitivity disks. The only ground for such an inter-

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[21] Annual Report, Food and Drug Administration, 1950, Kleinfeld & Dunn, Federal Food, Drug and Cosmetic Act, 1953-1957, pp. 575, 624. To the same effect is Notice of Judgment under Federal Food, Drug and Cosmetic Act, no. 4667 (Injunction against the device, D. Calif., 1956).

pretation would be that the disk is used, or intended for use, in the treatment of disease. Logic, the expert testimony, and the findings of the district court show that it is not so used or intended; that its use is as a part of a laboratory testing procedure yielding information which may be used by physicians as a guideline to the changing or selection of an appropriate antibiotic drug to treat patients who have not responded to initial therapy.

For the reasons stated, it is respectfully submitted therefore that the decisions below were clearly correct and that the petition for a writ of certiorari should be denied.

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